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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/527,781	03/31/2006	Robert Savit	UM-09752	9565
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Casimir Jones, S.C. 2275 DEMING WAY, SUITE 310 MIDDLETON, WI 53562				
EXAMINER				
TOYH, KAREN E				
ART UNIT		PAPER NUMBER		
3735				
MAIL DATE		DELIVERY MODE		
08/02/2010		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/527,781

**Applicant(s)**

SAVIT ET AL.

**Examiner**

KAREN E. TOTH

**Art Unit**

3735

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 3 June 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-21 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/CD)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Response to Amendment***

1. The declaration filed on 3 June 2010 under 37 CFR 1.131 has been considered but is ineffective to overcome the Sackellares reference.

The evidence submitted is insufficient to establish diligence from a date prior to the date of reduction to practice of the Sackellares reference to either a constructive reduction to practice or an actual reduction to practice. The evidence does not provide any dates other than the statements provided by the inventors merely claiming that the reduction to practice pre-dates Sackellares' filing. This is insufficient because it does not provide any support for reasonable diligence as required by MPEP 715.07 III, Which states, in part:

A conception of an invention, though evidenced by disclosure, drawings, and even a model, is not a complete invention under the patent laws, and confers no rights on an inventor, and has no effect on a subsequently granted patent to another, **UNLESS THE INVENTOR FOLLOWS IT WITH REASONABLE DILIGENCE BY SOME OTHER ACT**, such as an actual reduction to practice or filing an application for a patent. *Automatic Weighing Mach. Co. v. Pneumatic Scale Corp.*, 166 F.2d 288, 1909 C.D. 498, 139 O.G. 991 (1st Cir. 1909).

Further, MPEP 715.07(a) requires some evidence of facts establishing diligence. The absence of any dates in the present affidavit makes it impossible to establish diligence between the reduction to practice and filing.

### ***Claim Rejections - 35 USC § 102***

2. Claims 1-3, 5-14, and 16-21 rejected under 35 U.S.C. 102(e) as being anticipated by Sackellares (US 2004/0122335).

Regarding claim 1, Sackellares discloses a system for predicting ictal onset in a subject comprising first and second data sensors configured to be positioned on the scalp of a subject, where one is near an ictal onset focal point and the other is remote from the first sensor (figures 4A and 4B; paragraphs [0078]-[0079]), and a processor configured to analyze data collected at more than one time point from the sensors (paragraph [0026]; element 1210), where the sensor performs nonlinear manipulation of the data to produce a plurality of marginal predictability values for each time point, and the processor is configured to determine the difference between the marginal predictability values (paragraphs [0025], [0026], [0040], [0045], [0055]-0057], [0069]), where a decrease in the difference between values is predictive of ictal onset (entire document, with particular emphasis on paragraphs [0089], [0096], [0101]). The Examiner notes that Applicant has not provided a specific definition for "near" - given that Sackellares provides a plurality of electrodes on the subject's scalp, any one of them may be considered "near" a focal point. The Examiner also notes that divergence is the opposite of convergence (entrainment), so a decrease in divergence is the same as an increase of convergence.

Regarding claim 2, Sackellares further discloses the sensors comprising electrodes (paragraphs [0078]-[0079]).

Regarding claim 3, Sackellares further discloses the electrodes being used to record electroencephalogram data from the subject (paragraph [0040]).

Regarding claim 5, Sackellares further discloses collecting data at at least three time points (figure 2).

Regarding claims 6 and 7, Sackellares further discloses a subject warning device configured to receive information predictive of an ictal onset from the processor (paragraphs [0024], [0047])

Regarding claim 8, Sackellares further discloses the warning device comprising at least one audible or visual alarm (paragraph [0095]).

Regarding claim 9, Sackellares further discloses the processor comprising a computer readable memory (paragraph [0050]).

Regarding claim 10, Sackellares further discloses an anti-seizure agent administering device in communication with the processor that is configured to administer an anti-seizure agent to the subject (paragraphs [0103]-[0105]).

Regarding claim 11, Sackellares further discloses the anti-seizure agent being an electrical stimuli device (paragraph [0105]).

Regarding claim 12, Sackellares discloses a method of predicting ictal onset in a subject comprising providing a system with first and second data sensors configured to be positioned on the scalp of a subject, where one is near an ictal onset focal point and the other is remote from the first sensor (figures 4A and 4B; paragraphs [0078]-[0079]), and a processor configured to analyze data collected at more than one time point from the sensors (paragraph [0026]; element 1210), where the sensor performs nonlinear manipulation of the data to produce a plurality of marginal predictability values for each time point, and the processor is configured to determine the difference between the marginal predictability values (paragraphs [0025], [0026], [0040], [0045], [0055]-0057, [0069], [0089], [0096], [0101]), obtaining marginal predictability values for more than

one time point, and determining the difference between the values, where a decrease in the difference between values is predictive of ictal onset (paragraphs [0089], [0096], [0101]). The Examiner notes that Applicant has not provided a specific definition for "near" - given that Sackellares provides a plurality of electrodes on the subject's scalp, any one of them may be considered "near" a focal point. The Examiner also notes that divergence is the opposite of convergence (entrainment), so a decrease in divergence is the same as an increase of convergence.

Regarding claim 13, Sackellares further discloses the sensors comprising electrodes (paragraphs [0078]-[0079]).

Regarding claim 14, Sackellares further discloses the electrodes being used to record electroencephalogram data from the subject (paragraph [0040]).

Regarding claim 16, Sackellares further discloses collecting data at at least three time points (figure 2).

Regarding claims 17 and 18, Sackellares further discloses a subject warning device configured to receive information predictive of an ictal onset from the processor (paragraphs [0024], [0047])

Regarding claim 19, Sackellares further discloses the warning device comprising at least one audible or visual alarm (paragraph [0095]).

Regarding claim 20, Sackellares further discloses an anti-seizure agent administering device in communication with the processor that is configured to administer an anti-seizure agent to the subject (paragraphs [0103]-[0105]).

Regarding claim 21, Sackellares further discloses the anti-seizure agent being an electrical stimuli device (paragraph [0105]).

***Claim Rejections - 35 USC § 103***

3. Claims 4 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sackellares, as applied above, and further in view of Boling (US 2003/0195602).

Sackellares discloses all the elements of the claimed inventions, as described above, except for the plurality of time points being separated by ten minute intervals. Boling teaches measuring biosignals to predict an ictal onset in a subject where the measurements are taken at time points separated by non-recording intervals (paragraphs [0203], [0207]), in order to reduce the amount of data captured by the system. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have configured the system of Sackellares to capture data at time points separated by non-recording intervals, as taught by Boling, in order to reduce the data captured by the system. The Examiner notes that Sackellares and Boling do not expressly disclose the interval between measurements being ten minutes; at the time the invention was made, it would have been an obvious matter of design choice for a person of ordinary skill in the art to separate measurements by ten minutes because the Applicant has not disclosed that the exact interval between measurements provides a particular advantage, is for a particular purpose, or solves a stated problem. Moreover, it appears that the interval of Boling, or Applicant's interval, would perform equally well to minimize measurements. Accordingly, it would have been prima facie

obvious to one of ordinary skill in the art at the time the invention was made to have modified Sackellares and Boling to take measurements at ten minute intervals, because such a modification would have been considered a mere design consideration that fails to patentably distinguish over Sackellares and Boling.

### ***Response to Arguments***

4. Applicant's arguments filed 3 June 2010 have been fully considered but they are not persuasive. The arguments presented are contingent upon entry of the declaration under 1.131. Since the declaration has been found ineffective to overcome the Sackellares reference, the arguments are moot and the rejections stand as final.

### ***Conclusion***

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.



6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to KAREN E. TOTH whose telephone number is (571)272-6824. The examiner can normally be reached on Mon thru Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor II can be reached on 571-272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Patricia C. Mallari/  
Primary Examiner, Art Unit 3735

/K. E. T./  
Examiner, Art Unit 3735